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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/581,770

12/29/2000

Kuber T. Sampath

00960-520PRO

7664

28120

7590

12/03/2004

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EXAMINER

LI, RUIXIANG

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/581,770

Applicant(s)

SAMPATH ET AL.

Examiner

Ruixiang Li

Art Unit

1646

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED on 11/01/2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 01 November 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

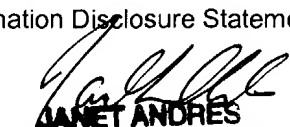
Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 20,22-24,26,31 and 34.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

  
JANET ANDRES  
PRIMARY EXAMINER

Continuation of 2. NOTE: The amendment presents 7 exhibits, which are all new publications and require significant further consideration.

Continuation of 5. does NOT place the application in condition for allowance because: All the pending rejections are maintained.

Beginning at page 5 of Applicants' response, Applicants argue that the rejection of claims 20, 22-24, 26, 31, and 34 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 19, and 20 of U.S. Patent No. 6,498,142 B1, as set forth at pages 4-5 of the office action mailed on December 17, 2003, is based on the alleged dominance of the claims from the subject application over the claims of the '142 and thus is not proper. This is not found to be persuasive because the presence of domination does not preclude double patenting (MPEP 804, II, top of right column of page 804). In the instant case, claims 1-4, 19, and 20 of U.S. Patent No. 6,498,142 B1 falls entirely within the scope of instant claims 20, 22-24, 26, 31, and 34, or in other words, claims 20, 22-24, 26, 31, and 34 are anticipated by claims 1-4, 19, and 20 of U.S. Patent No. 6,498,142 B1. Thus, the rejection is proper and maintained.

Beginning at page 6 of applicants' response, Applicants argue that the Examiner fail to establish a lack of enablement. Applicants submit that the Examiner fails to describe why the amended claims as too broad in light of the specification, and why the claims containing the term "restoring the cellular phenotype" is too broad. Applicants note that the claims have been amended to recite functional limitations. This is not persuasive for the following reasons, as well as for the reasons of record. First, it is noted that the amended claims recite functional limitations for the morphogen. However, the instant disclosure of human OP-1 is not sufficiently representative of the recited genus of morphogens and there is no defined relation between function and structure of the morphogen. For example, among amino acid residues 330-431 of SEQ ID NO: 8, it is not clear which 40 or 30 amino acid residues may be altered. Thus, the instant disclosure fails to enable an artisan to use the genus of morphogen in the claimed method. Secondly, the office actions of record clearly described why the the term "restoring the cellular phenotype" is too broad (see, e.g., the middle of page 7 of the office action mailed on 12/17/2003. Accordingly, the scope of enablement rejection is justified and maintained.

At the bottom of page 9, Applicants submit 7 new publications in support their argument. The references have not been considered, because they require significant further consideration.

Beginning at page 11 of Applicants' response, Applicants argue that the Examiner concedes that applicant's claims amendment did overcome the hepatocyte rejection previously raised, and proceeds to set forth a new ground for the rejection. This is not found to be persuasive. The previous office action (page 7) states the following:

Applicants argue that the amended claims recite specific cell types, i.e., lung cells, heart cells, blood vessel cells, renal cells, stomach cells and intestinal cells, but do not recite hepatocytes. This has been fully considered, but is not deemed to be persuasive because Kuberasampath et al. not only teach the use of morphogens to maintain liver function in a mammal, but also teach treatment of transplant tissues, e.g., liver, lung, kidney, pancreas, heart, etc., to provide a cytoprotective effect to the tissue (line 17-23 of page 18). Kuberasampath et al. further teach the expression of OP-1 in kidney-related tissue, brain, heart, lung tissues (lines 24-27 of page 91). Thus, the reference of Kuberasampath et al. still meets the limitations of the amended claims.

It is also noted that the Examiner made the above comments in response to Applicants' argument and amendment. If Applicants consider it as a new ground of rejection, it is necessitated by Applicants' argument and amendment.

At the middle of page 12, Applicants argue that claims 20 and 31 recite the use of a morphogen to treat a cell affected by disease, damage, or age. This feature of the claimed invention is not anticipated by the '449 publication. This is not persuasive because the currently claimed invention, in essence, is drawn to a method comprising administering the a subject an effective amount of a morphogen or contacting a cell with an effective amount of a morphogen, there are no limitations on the dosage, subject, and the structure of the morphogen. Since the cited reference teaches such a method, the claims are anticipated and a rejection is required.